

- Brasil, no ano de 2012. **MÉTODOS:** Foi delineado em janeiro/2012 um cenário sob a perspectiva da operadora e com os pacientes potenciais de utilização de IMB-EV em primeira linha de tratamento para (Artrite Reumatoide, Espondilite Anquilosante, Artrite Psoriática e Doença de Crohn) em sua maior posologia/doses. Somente custos diretos foram considerados em Reais (\$) e utilizou-se um paciente padrão com peso médio de 70 kg para o IMB-EV peso-dependente na dose. A análise da incidência das doenças na cartela epidemiológica de clientes da operadora permitiu uma extrapolação para determinação do custo/tratamento em relação ao número de infusões em relação a cada tipo de IMB-EV (Infliximab, Tocilizumab, Abatacepte). Utilizou-se Brasindice 741 para precificação dos medicamentos. **RESULTADOS:** A partir dos dados coletados foram projetados atendimentos de 50 pacientes em uso de infliximabe com um custo anual de R\$ 5.051.886,00 e per capta de R\$ 101.037,72. Em uso de Tocilizumab o custo anual seria de R\$ 2.338.944,00 (per capta de R\$ 46.778,88) e com Abatacepte o custo anual seria de R\$ 2.997.498,00 (per capta R\$59.949,96). Assim o total geral da incorporação com IMB-EV teve um custo projetado de R\$ 10.388.328,00. **CONCLUSÕES:** A avaliação de custos com medicamentos de alto impacto nos orçamentos das instituições de saúde, como os imunobiológicos, nas operadoras tem se tornado uma importante ferramenta para um planejamento estratégico e sustentável financeiramente. A partir das análises e monitorizações, teve-se a tomada de decisão para inclusão de outros IMB subcutâneos como Etanercept, Golimumab e Certolizumabe, os quais podem apresentar uma relação custo-minimização mais favorável.

#### PMS4

##### COMPARING COSTS PER CLINICAL REMISSION OF TOCILIZUMAB MONOTHERAPY VERSUS ADALIMUMAB MONOTHERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS: A BRAZILIAN PRIVATE PERSPECTIVE

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**OBJECTIVES:** Rheumatoid Arthritis (RA) is an autoimmune disease that causes chronic inflammation of the joints. Disease progression leads to a significant socioeconomic impact for the individual and for society. In Brazil, there are eight approved biologic drugs indicate to treat patients with moderate/severe RA that presented previous inadequate response to therapy with DMARDs, including tocilizumab (TCZ) and adalimumab (ADA). ADACTA trial (Gabay et al, 2012) showed positive results related to TCZ monotherapy for the treatment of moderate/severe RA in patients who presented inadequate response to methotrexate therapy or were MTX intolerant. This study aims to evaluate costs of TCZ monotherapy vs. ADA monotherapy to achieve remission after one year of treatment for adult RA, according to ACR70 and DAS28 outcomes. **METHODS:** An economic evaluation based on ADACTA study was performed. Drugs ex-factory prices were used to estimate treatment costs. Regimen was 8 mg/kg every 4 weeks TCZ and 40 mg every 2 weeks ADA. Costs to achieve remission in one year according to ACR70 and DAS28 outcomes were compared. The study was conducted from a Brazilian private health care perspective, considering only drug costs. Costs were reported in Brazilian Reais (BRL1.00=USD0.51 Feb/2013). **RESULTS:** Annual costs were BRL39,100.06 TCZ vs. BRL63,134.76 ADA. After one year of treatment, ACR70 response rates were achieved in 32.50% in TCZ group and 17.90% in ADA group. DAS28 remission was achieved in 39.90% and 10.50% in TCZ and ADA group, respectively. TCZ presented better results in costs per clinical remission than ADA (ACR70 BRL120,307.88 vs. BRL352,708.16 and DAS28 BRL97,995.14 vs. BRL601,283.43). **CONCLUSIONS:** TCZ presented better response rates in both ACR70 and DAS28 outcomes and lower annual costs per clinical remission compared to ADA, suggesting that TCZ is a better single-agent alternative to treat moderate/severe rheumatoid arthritis in Brazilian private health care system.

#### PMS5

##### ANALYZING COSTS PER CLINICAL REMISSION OF TOCILIZUMAB MONOTHERAPY VERSUS ADALIMUMAB MONOTHERAPY IN RHEUMATOID ARTHRITIS FROM A PUBLIC PERSPECTIVE IN BRAZIL

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**OBJECTIVES:** Rheumatoid Arthritis (RA) is a chronic systemic autoimmune disease which affects around 0.5% of adult population worldwide. ADACTA (Gabay et al, 2012) is the first study designed to compare two approved biologic drugs in monotherapy for the treatment of RA. The trial compared tocilizumab monotherapy (TCZ) vs. adalimumab monotherapy (ADA) and presented results that support TCZ alone as a single-agent therapy for RA patients who are either intolerant to methotrexate (MTX) or in whom previous MTX therapy was inadequate. Based on ADACTA, this study aims to compare annual costs per clinical remission of TCZ vs. ADA in moderate/severe adult RA treatment considering ACR70 and DAS28 outcomes. **METHODS:** Remission data of ACR70 and DAS28 outcomes were taken from ADACTA study. Annual costs of TCZ and ADA therapies considered labeled dosage and public drugs acquisition's prices. Based on these data, costs per clinical remission after one year of treatment were compared. Regimen was 8 mg/kg every 4 weeks TCZ and 40 mg every 2 weeks ADA. The average weight of 67 kg was assumed. A public health care system perspective was considered and only drug costs were evaluated. Drug acquisition prices were assessed from public disclosures. Costs were reported in Brazilian Reais (BRL1.00=USD0.51 Feb/2013). **RESULTS:** After one year of treatment, annual costs were BRL26,898.56 ADA and BRL19,945.90 TCZ. Therapy with TCZ as a single-agent showed better response rates in both outcomes (ACR70 32.50% TCZ vs. 17.90% ADA and DAS28 39.90% TCZ vs. 10.50% ADA). Costs per clinical remission considering ACR70 results were BRL61,372.00 TCZ vs. BRL150,271.28 ADA. Costs per clinical remission of DAS28 were BRL49,989.72 TCZ vs. BRL256,176.76 ADA. **CONCLUSIONS:** The analysis suggests that TCZ represents an effective strategy to treat moderate/severe adult RA patients in Brazil's public health care system and presents lower costs per clinical remission compared to ADA.

#### PMS6

##### COSTOS ASOCIADOS A EVENTOS CARDIOVASCULARES EN PACIENTES CON ARTRITIS REUMATOIDE AFILIADOS AL RÉGIMEN SUBSIDIADO EN COLOMBIA

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**OBJETIVOS:** Los pacientes con Artritis Reumatoide (AR) tienen un número importante de manifestaciones extrarticulares incluyendo la enfermedad cardiovascular, la cual conduce del 30-50% de todas las muertes. El objetivo de este trabajo es estimar los costos asociados a eventos agudos (infarto al miocardio y pericarditis) y crónico (falla cardíaca) de la enfermedad cardiovascular en pacientes con AR en Colombia. **METODOLOGÍAS:** Este estudio se realizó desde la perspectiva del tercer pagador. Se identificaron los eventos generadores de costo de guías de atención aprobadas por el ministerio de salud, con ayuda de un experto clínico se construyeron los casos tipo de infarto al miocardio, pericarditis y falla cardíaca, se utilizó un costeo por actividades siguiendo la metodología del bottom-up, para la valoración de procedimientos se emplearon los manuales tarifarios ISS y SOAT, los costos de los medicamentos se tomaron del SISMED y el costo de los dispositivos médicos se obtuvo de licitaciones públicas. Todas las cifras monetarias se expresan en pesos colombianos de 2013. La prevalencia de la AR y el riesgo de ocurrencia de los eventos cardiovasculares se tomaron de la literatura. Los datos de aseguramiento provienen de estadísticas nacionales. **RESULTADOS:** El costo promedio de atención de los eventos cardiovasculares objeto de estudio en pacientes con AR fueron: infarto al miocardio \$ 8.518.192 (procedimientos: \$ 4.364.209; medicamentos: \$ 4.004.331; insumos: \$ 149.652); pericarditis \$ 2.638.233 (procedimientos: \$ 2.430.875; medicamentos: \$ 207.357); falla cardíaca \$ 26.435.947 (procedimientos: \$ 9.348.420; medicamentos: \$ 17.087.526). Los costos globales de atención en pacientes con AR afiliados al régimen subsidiado de los eventos cardiovasculares de interés serían: infarto al miocardio \$ 38.106.493.677; pericarditis \$ 5.447.190.660; y falla cardíaca \$ 54.582.612.447. **CONCLUSIONES:** La enfermedad cardiovascular en pacientes con AR representa una carga económica de gran impacto para el régimen subsidiado en el sistema de salud Colombiano.

#### PMS7

##### COSTOS ASOCIADOS A NEUMONÍA SEVERA Y TUBERCULOSIS EN PACIENTES CON ARTRITIS REUMATOIDE QUE HAN RECIBIDO TRATAMIENTO CON TERAPIA BIOLÓGICA ANTI-TNF

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**OBJECTIVOS:** Los pacientes con artritis reumatoide (AR) tienen un mayor riesgo de padecer infecciones severas, debido a factores de mal pronóstico de la enfermedad que han sido identificados como predictores de infección y al tratamiento farmacológico con inmunosupresores. En la literatura se encuentran reportados como eventos adversos frecuentes respecto a infecciones, la neumonía severa y la tuberculosis (TBC) en pacientes que han recibido tratamiento con terapia biológica anti-TNF, el objetivo de este trabajo es presentar una estimación de costos médicos directos de dichos eventos. **METODOLOGÍAS:** Este estudio se realizó desde la perspectiva del tercer pagador. Los eventos generadores de costo para neumonía severa se identificaron a partir de una guía de práctica clínica Colombiana y para TBC se empleó un protocolo de manejo avalado por el ministerio de salud. Se construyeron los casos tipo para cada patología con ayuda de un clínico experto y se utilizó un costeo por actividades siguiendo la metodología bottom-up. La valoración de los procedimientos se realizó teniendo en cuenta los manuales tarifarios ISS y SOAT, los costos de los medicamentos se tomaron del SISMED y el costo de los dispositivos médicos se obtuvo de licitaciones públicas. Todas las unidades monetarias se expresan en dólares americanos (1 US\$ = 1.785 COP). **RESULTADOS:** El costo promedio de atención de la neumonía en pacientes que van a la unidad de cuidado intensivo (50%) fue US\$ 2410 (procedimientos US\$ 2194; medicamentos US\$ 191; insumos US\$ 25). El costo promedio de atención de la neumonía en pacientes que van a hospitalización (50%) fue US\$ 1854 (procedimientos US\$1425; medicamentos US\$392; insumos US\$ 37). El costo de atención de TBC fue US\$16,438 (procedimientos US\$ 299; medicamentos US\$ 16,139). **CONCLUSIONES:** Los costos asociados a la atención de la neumonía severa y TBC representan un gran impacto económico para el sistema de salud.

#### PMS9

##### CUSTOS DAS FRATURAS OSTEOPORÓTICAS NO SISTEMA PÚBLICO DE SAÚDE BRASILEIRO

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**OBJETIVOS:** Descrever o custo do tratamento hospitalar das fraturas de baixa energia, típicas da osteoporose, no Sistema Único de Saúde do Brasil. **MÉTODOS:** Foi realizado um estudo de custos por procedimentos nas unidades do complexo de urgência e emergência da Fundação Hospitalar do Estado de Minas Gerais (Fhemig). O período de coleta dos dados foi de janeiro a maio de 2012. O estudo foi composto de cinco etapas sequenciais, que englobam: i. Identificação e definição dos macro-processos, processos e atividades relacionados às fraturas de quadril, ombros, punhos e vertebrais, decorrentes da osteoporose; ii. Elaboração de Mapeamento de Processos típicos de pacientes acometidos pela doença submetidos a tratamento cirúrgico; iii. Identificação dos recursos consumidos em cada atividade, como tempo gasto para cada atividade, materiais médico-hospitalares, órteses e próteses; iv. Construção da base de informações interligada com o Sistema de Gestão Hospitalar (SIGH – Custos ABC); e v. Realização de Painel de Especialistas para validação do estudo. Os valores foram descritos em dólar americano (31 de março de 2012 – taxa de cambio: 1 dólar = 1,82 real). **RESULTADOS:** Os maiores custos encontrados foram para as fraturas vertebrais, seguido das fraturas dos quadris, ombros e punhos. Custos de fraturas vertebrais variaram de \$10,054.57 a 20,313.73; das fraturas de

quadris de \$2,126.41 a 11,012.42. Os custos para as fraturas de ombros variaram de \$1,355.64 a 4,436.57. E, custos das fraturas de punhos variaram de \$454.75 a 3,869.94. O maior percentual do custo, na maioria das vezes, estava relacionado às próteses e ao tempo de permanência pós-cirúrgico no ambiente hospitalar. **CONCLUSÕES:** Apesar de os maiores custos estarem relacionados às fraturas vertebrais, os desfechos clínicos mais relevantes da osteoporose são as fraturas de quadris, devido à sua elevada incidência. Fraturas osteoporóticas são, em grande parte, evitáveis, a partir do controle dos fatores de risco e medicação preventiva adequada.

#### PMS10

##### CUSTO-EFETIVIDADE DO TRATAMENTO PARA OSTEOPOROSE NA POS-MENOPAUSA NO BRASIL

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**OBJETIVOS:** Realizar uma avaliação de custo-efetividade dos medicamentos disponíveis para o tratamento da osteoporose na pós-menopausa, sob a perspectiva do Sistema Único de Saúde, do Brasil. **MÉTODOS:** Utilizou-se um modelo de Markov para simular a progressão da osteoporose na pós-menopausa presumindo-se uma coorte hipotética de mulheres de diferentes faixas etárias (40-49 anos, 50-59 anos, 60-69 anos, 70-79 anos e 80 ou mais) com fraturas prévias. O modelo levou em consideração a eficácia do tratamento nos diferentes sítios de fraturas (quadris, punhos, ombros e vértebras). Foram comparados o alendronato, risedronato, ibandronato, calcitonina, raloxifeno, calcitriol, teriparatida e denosumabe com não oferecer tratamento medicamentoso. O modelo foi utilizado para estimar os benefícios clínicos em termos de anos de vida ganhos e os custos associados ao tratamento medicamentoso. Os dados de eficácia foram baseados em revisões sistemáticas com metanálise; os custos do tratamento e com internações decorrentes das fraturas referiram-se aos custos do Sistema Único de Saúde. O tempo de seguimento foi de 50 anos ou até a morte. Utilizou-se taxa de desconto de 5% nos custos e benefícios. Foram feitas análises de sensibilidade probabilística e considerando-se diferentes taxas de desconto. **RESULTADOS:** As estratégias terapêuticas não foram custo-efetivas na faixa etária de 40-49 anos. Aos 50-59 anos, foram custo-efetivos o alendronato e denosumabe; nas faixas etárias mais avançadas (60 anos ou mais), somente o alendronato foi custo-efetivo. **CONCLUSÕES:** As estratégias terapêuticas foram custo-efetivas para algumas situações. E, apesar de existirem diferentes opções terapêuticas para o tratamento da osteoporose na pós-menopausa, poucas tem efeito em todos os sítios de ação. Nenhuma das estratégias apresentou-se cost-saving.

#### PMS11

##### ASSESSMENT OF COST-EFFECTIVENESS MODELS FOR BIOLOGICS IN THE MANAGEMENT OF PSORIATIC ARTHRITIS

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**OBJECTIVES:** Given biological therapies in psoriatic arthritis (PsA) treatment paradigm are expensive, cost-effectiveness evaluations can be a valuable tool in payer health care decision making. We sought to review the economic evidence and cost-effectiveness of all available biologics developed for treatment of PsA. **METHODS:** We conducted a structured literature search of published and unpublished literature from year 1996 to 2012. We included modeling and other economic studies that assessed cost-effectiveness of biologics and excluded studies that evaluated therapies other than biologics. **RESULTS:** A total of 9 studies involving moderate to severe active PsA patients were analyzed. Most of the cost-effectiveness studies were conducted in the UK (N=6) using direct payer perspective. As no head-to-head trials between biological therapies were present, either indirect comparison with Bayesian technique or network meta-analyses were used to synthesize evidence. Treatment clinical effectiveness was measured by psoriatic arthritis response criteria (PsARC) and/or psoriasis area and severity index (PASI). Functional status was measured by health assessment questionnaire (HAQ). Decision analytical model with underlying Markov modeling was considered by majority of the studies to build the cost-effectiveness model using cohort of patients, while few studies used patient level simulations. Disease-modifying anti-rheumatic drugs (DMARDs) were primarily considered as comparators. Time horizon varied from 10 years to lifetime. All studies employed quality adjusted life years (QALYs) as their measure of effectiveness. Costs and QALYs discounting rate varied from 3.5 to 6% and 1.5 to 3.5% respectively. Incremental cost-effectiveness ratio per QALY varied from £17,000 to £40,000. **CONCLUSIONS:** Although biologics are considered expensive, they improve patient's quality of life in the long-run. Existing cost-effectiveness studies have differences in their assumptions and methodologies, and provide valuable inputs towards building the set of disease related parameters. Next generation of biologic therapies in the near future can benefit from these analyses.

#### PMS12

##### ASSESSMENT OF COST-EFFECTIVENESS MODELS FOR BIOLOGICS IN THE MANAGEMENT OF SEVERE ANKYLOSING SPONDYLITIS

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**OBJECTIVES:** Current biologics provide effective clinical benefits to patients with ankylosing spondylitis (AS). We sought to review economic evidence supportive of cost-effective evaluation for currently available biologics developed for treatment of severe AS that aid in disease management decision-making. **METHODS:** A structured literature search of published and unpublished literature from year 1996-2012 was conducted. We included modeling and other economic studies that assessed cost-effectiveness of biologics and excluded studies evaluating other therapies. **RESULTS:** Ten studies (infliximab=5, etanercept=2, infliximab and etanercept=1, adalimumab=1, golimumab=1) were analyzed. Majority of studies (N=7) were conducted from societal perspective. Health payer perspective was employed

by 2 studies and one study incorporated both. Cohort simulation of patients with severe AS was employed to build cost-effectiveness model by most of the studies and few used patient-level simulation. Non-steroidal anti-inflammatory drugs were considered as comparators in all economic models. Studies employed quality adjusted life years (QALY) as their unit of outcome. Euro-quality-of-life-5 dimensions was used as the instrument for quality weightings by most studies and health utilities index-3 and general health rating scale were used by others. Bath ankylosing spondylitis disease activity index and Bath ankylosing spondylitis functional index were used as response and efficacy parameters. Costs and QALYs discounting rate varied from 3%-6% and 1.5%-5% respectively. Over a longer time horizon (25-40 years), the incremental cost-effectiveness ratio per QALY varied from €7,500-€56,000 for infliximab, €22,000-€32,000 for etanercept, €23,000 for adalimumab, and €30,000 for golimumab. **CONCLUSIONS:** Although biologics are considered expensive, they are the only approved therapy options for patients with severe AS. Even though existing cost-effectiveness studies have differences in their assumptions and methodologies, they do provide valuable inputs towards building set of disease related parameters useful for economic evaluation of next generation biologic agents.

#### PMS13

##### COST-EFFECTIVENESS ANALYSIS OF ETANERCEPT IN THE TREATMENT OF RHEUMATOID ARTHRITIS IN INSTITUTIONAL MARKET IN ECUADOR

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**OBJECTIVES:** Rheumatoid arthritis is an autoimmune, inflammatory and chronic disease associated with significant morbidity. Due its chronic and progressive nature, functional limitations and physical disability cause an important social and economic impact. In Ecuador, the prevalence of AR is 0.9%; The incidence is higher in women (6.4:1) and the average age is 53.6 years, representing a Public Health problem. Biologic treatments represent a therapeutic alternative for patients who failed disease-modifying antirheumatic drugs. However, their high cost and the high risk of tuberculosis are the challenges for clinicians and decision makers. The aim of this study was to assess the cost-effectiveness of biologic alternatives in Ecuador from an institutional perspective. **METHODS:** A Markov model was developed to simulate the clinical course of patients treated with etanercept (25mg twice a week), adalimumab (40 mg every 15 days) and infliximab (3mg/kg initial and at 2<sup>nd</sup> and 6<sup>th</sup> week, every 8 weeks) as first-line therapies combined with Methotrexate 20 mg/kg per week after DMARDs failure, as well as associated costs over one-year period. Effectiveness measures were: proportion of patients achieving 70% improvement in both, tender or swollen joint counts following the ACR70 criteria and quality adjusted life years gained. Costs considered included: biologics, concomitant drugs, medical follow-up and side effects management. Clinical response of alternatives was extracted from published literature, while costs were collected from Official Ecuadorian databases. **RESULTS:** The cost-effectiveness analysis showed the utility in QALYs gained of etanercept, adalimumab and infliximab is 0.79; 0.77; and 0.73 respectively, the net costs are: USD\$ 17092.39 for Etanercept; USD\$ 17,940.39 for Adalimumab and USD\$32979.60 for Infliximab. Resulting etanercept the dominant option. **CONCLUSIONS:** The cost effectiveness analysis results determinate that etanercept is the most cost effectiveness option. Due the less production of adverse events including tuberculosis, easy and ambulatory application and differential price for institutional market.

#### PMS14

##### EVALUACIÓN DE COSTO-EFECTIVIDAD DE CERTOLIZUMAB PEGOL COMPARADO CON ETANERCEPT EN EL TRATAMIENTO DE ARTRITIS REUMATOIDEA EN COLOMBIA

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**OBJECTIVOS:** Los Anti TNF alfa son terapia de primera línea para el tratamiento de pacientes con Artritis Reumatoidea Activa (AR) con inadecuada respuesta a metotrexato u otros DMARDs no biológicos, el objetivo del presente estudio es evaluar la costo efectividad de certolizumab pegol (CZP) en comparación con el anti TNF incluido en el listado de medicamentos del plan de salud en Colombia etanercept (ETA), bajo la perspectiva del sistema de salud con un horizonte temporal de un año. **METODOLOGÍAS:** Se construyó modelo basado en árbol de decisiones no probabilístico en Excel, la medida de efectividad fue la tasa de respuesta ACR20 a la semana 52 la cual fue extraída de los estudios pivoteales de cada una de los medicamentos (TEMPO y RAPID 1), se siguió la metodología para comparaciones indirectas de Glenney et al. en donde se ajusta por metotrexato como comparador común. Se incluyen costos directos, el costo anual de la terapia se estimó usando los valores de la Circular 04 de Noviembre de 2012 de la Comisión Nacional de Precios y Dispositivos Médicos y las tarifas SOAT 2012 para gastos médicos complementarios. Se calculó la razón de costo efectividad promedio e incremental y se realizó análisis de sensibilidad con +/- 10% de los valores del caso base. **RESULTADOS:** El costo anual fue estimado en 19.270USD para ETA y 25.692USD para CZP, la tasa de respuesta ACR 20 ajustada fue de 45% para ETA Vs 77% para CZP, la razón de costo efectividad fue de 42.755USD para ETA y 33.434USD para CZP y el costo por respondedor adicional de CZP comparado con ETA es 201 USD, las conclusiones se mantienen en el análisis de sensibilidad. **CONCLUSIONES:** En Colombia certolizumab pegol resulta costo efectivo frente a etanercept en pacientes con Artritis Reumatoidea activa que han tenido respuesta inadecuada a DMARDs no biológicos.

#### PMS15

##### ESTIMATED COST EFFECTIVENESS OF LOWER-DOSE SUBMICRON DICLOFENAC COMPARED WITH TRADITIONAL DICLOFENAC IN BRAZIL

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